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| CATALYST LAW GROUP, APC 9710 SCRANTON ROAD, SUITE S-170 SAN DIEGO, CA 92121 | | | | |
| EXAMINER | | | | |
| TATE, CHRISTOPHER ROBIN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1655 | | | | |

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,131

Applicant(s)

GRANDICS ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-38 is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 13 July 2006 is acknowledged and has been entered. Claims 1-38 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-19 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention - for the reasons set forth in the previous Office action which are restated below.

Claims 1-19 are not enabled because the specification fails to teach (thus, lacks an adequate written description) what the "plant Soma" is actually defining with respect to a particular botanical plant and, thus, also fails to teach how to make the essential recited anti-cancer ingredient: "an aqueous extract" thereof, as recited in independent claims 1 and 7.

As evidenced by numerous Internet references cited in the Information Disclosure Statement filed (IDS) filed 15 March 2004, there is great confusion and controversy as to what constitutes the ancient mystical "plant Soma". For example, Dr. Padhy from the Dept. of Botany of Orissa's Government Science College states that although some US scientists have proposed the mushroom *Amanita muscaria* as being the Soma plant, Dr. Padhy believes that the Soma plant is not this mushroom, and further discloses that "[d]uring the last two centuries, about 20 plants have been identified as the soma plant. The old school of thought has tried to overcome the

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mythological concept of Soma, correlating it with plants like *Sarcostemma*, *Asclepias acida*, *Ceropegia elegans*, and *Cannabis sativa*" [see, e.g., 2001 Indian Express Newspapers (Bombay) Ltd. Internet article]; while others propose the "Soma plant" may be *Peganum harmala*, *Psiblcye cubensis*, ergotized grain, a combination thereof, or a mixture of several plants (see, e.g., Internet article titled "Ploughing the Clouds: The Search for Irish Soma"). Further, in a review of the book "Soma: The Divine Hallucinogen" (in an Internet article with the same heading) by David Spess, Dr. Peter Furst states that "[s]oma's devotees knew of many different kinds and even colors of soma drinks with different associations and purposes, so that soma botany and taxonomy cannot be reduced to a single sacred plant species" (see, e.g., page 2 of this Internet article); while R. Rudgley suggests that soma may yet be a combination of *Cannabis* and *Ephedra* (see, e.g., pages 2-3 of the Internet article titled "Soma from the Encyclopedia of Psychoactive Substances"). Still, other scientists (most notably R.G. Wasson) are convinced that the mushroom *Amanita muscaria* is indeed the Soma plant and include as evidence that "[n]o mention is made of its leaves, roots, blossoms, or seeds" (see, e.g., the first page of the Internet article titled "Soma: The Mushroom God") which is consistent with a mushroom, not a plant. However, the instant specification expressly teaches that the roots were the part of the plant used in preparing the disclosed aqueous extract (see, e.g., paragraph [0019] of the instant specification) which further creates confusion as to what Soma plant was actually used in preparing the instantly claimed/disclosed essential anti-cancer extract ingredient, since the *Amanita muscaria* mushroom does not have roots. On page 6, paragraph [0018], of the instant CIP Application, it is stated that the Applicant concurs with Dr. Paddy's analysis of Soma as set forth in the 2001 Indian Express Newspapers (Bombay) Ltd. Internet article (IDS reference:

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Internet article titled "Search for divine somarasa plant") and indicate that the Soma plant used in the instant invention is not the hallucinogenic mushroom *Amanita muscaria*. However, other than Dr. Paddy's (and Applicant's) belief that plant Soma is not the mushroom *Amanita muscaria*, this internet article by Dr. Paddy fails to reasonably teach what the Soma plant actually is (including its botanical genus or species) - i.e., as stated above, this internet article discloses that "[d]uring the last two centuries, about 20 plants have been identified as the soma plant. The old school of thought has tried to overcome the mythological concept of Soma, correlating it with plants like *Sarcostemma*, *Asclepias acida*, *Ceropegia elegans*, and *Cannabis sativa*". Although Dr. Paddy indicates in this internet article that "[t]he original plant, according to verdic literature, had 15ves which emerged and shed one by one keeping pace with the appearance of moon ...[i]t had a bulb, creeper like appearance and had milky secretion" (see 2nd page of internet article) it is apparent from this internet article, as well as the other references cited above, that at the time the claimed invention was made, one of skill in the art would not have been able to make and use the claimed invention - e.g., the skilled artisan would not have been able to reasonably determine what botanical plant the Soma plant actually was, nor how one of skill in the art would go about obtaining/possessing an actual sacred vedic Soma plant (as discussed by Dr. Paddy) as well as verifying its actual identity.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention as claimed because the instant specification fails to provide an adequate written description as to what botanical plant constitutes a Soma plant from which to make the claimed essential anti-cancer aqueous extract ingredient, nor how to obtain and verify the identity of such a plant.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For the reasons set forth above (under U.S.C. 112, first paragraph), it is unclear as to what the phrase "plant Soma" in claim 1 (line 2) and claim 6 (line 2) is actually defining - e.g., is this defining a plant and if it is a plant - what plant?

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

As set forth in the previous Office action, please note that the same USC 112, first and second paragraph rejections set forth above were made during the prosecution of parent Application No. 10227,006 (which went to Appeal) and that the USC 112, first paragraph rejection was upheld by the Board of Appeals in the parent Application (the Board affirmed that USC 112 first paragraph rejection - however, the Board did not examine the merits of the USC 112, second paragraph rejection since they affirmed the USC 112, first paragraph rejection).

For the record (and in the interest of compact prosecution), below are the arguments and responses as presented in the Examiner's Answer for parent Application No. 10/227,006 concerning to the same USC 112, first and second paragraph rejections set forth above:

'Appellant argues that the specification clearly defines Soma and also provides a source for a specific plant, which would enable one of ordinary skill in the art to practice the invention without undue experimentation; and further that the burden of the Patent and Trademark Office to show nonenablement has not been met for the rejection made by the Office because the statements expressing possible doubt as to the identity of Soma do not rise to the level of statements that create a sufficient level of doubt. Appellant also argues that the specification, including the examples, considered as a whole, clearly meet the standard required by the first paragraph of 35 USC 112; and that the invention is enabled because all that is required to provide enablement is that any mode of making and using the invention be recited in the specification. Appellant argues that this test is clearly met here by the examples of particular herbal compositions described in the specification and examples of their use, and that specific directions for the preparation and use of these compositions are given.

However, as discussed *supra*, other than disclosing within the instant CIP application that Appellants believe the Soma plant is not the mushroom *Amanita muscaria*, no specific plant source defining what the Soma plant actually is was found within the teachings of the instant specification, including within the instant Examples (which simply disclose that the "Soma extract" was utilized - see, e.g., paragraph [0042]). This appears to be a specious argument by Appellants in that the "Soma plant" does not and can not properly be used as a suitable means of defining the specific source of the Soma plant because, as discussed *supra*, the instant specification fails to provide an adequate written description of what constitutes the claimed Soma plant and, thus, it is

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totally unclear as to what the "plant Soma" is actually defining. That is, Appellants are apparently making a circular argument whereby the Soma plant is being used to define the Soma plant, which is an illogical and flawed argument with respect to the above USC 112 rejections because the instant specification never actually teaches what the Soma plant is to begin with. It should be noted that the 1999 Rig Veda publication referred to in paragraph [0014] as well as the 9th book of Rig Veda referred to in paragraph [0016] of the instant specification do not appear to adequately disclose and/or define what the Soma plant actually is (see, e.g., discussions noted above by Dr. Paddy with respect to verdic literature). In addition, although paragraph [0016] of the instant specification states that, alternatively, Soma extract is commercially available from A-D Research Foundation in Carlsbad, CA (which, based upon an internet search, appears to be a corporation owned by the Appellant), this statement fails to provide an adequate written description of (and, thus, fails to adequately define) the specific botanical source of this ancient mystical plant. Further, the specification as a whole fails to provide an adequate written description (as well as fails to adequately define) the particular botanical genus (much less the particular botanical species) actually used therein in preparing the claimed aqueous extract of the plant Soma. As discussed in detail above, based upon the evidence provided by the cited references, the skilled artisan would not have been able to reasonably determine what botanical plant the Soma plant actually was, nor how one of skill in the art would go about obtaining/possessing an actual sacred vedic Soma plant (as discussed by Dr. Paddy) as well as verifying its actual identity.

As such, the Patent Office has met the burden in showing that the claimed invention is not enabled for the reasons discussed *supra*.'

Applicant's arguments concerning the above USC 112 rejections have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicant argues that the claims as amended (i.e., amended claims 1 and 7) recite characteristics of the plant Soma as recited in the instant specification and that these characteristics are accepted by those of ordinary skill in the art as identifying characteristics. However, please note that the added new phrase "a plant with a creeper-like appearance and milky secretions" within amended claims 1 and 7 in no way adequately identifies (defines) what the "plant Soma" actually is, but instead only defines a couple of general characteristics that may (or may not) exist with the Soma plant, especially given that the instant specification states "The Soma plant is said to have milky secretions, a creeper-like appearance, and exist in two varieties according to Rig Veda" (see paragraph [0018] of the instant specification). All other arguments presented by Applicant have been adequately addressed above and in previous Office actions, and are not deemed persuasive for the reasoning set forth above.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

As set forth in the previous Office action, claims 20-38 are allowable. The prior art of record does not teach or reasonably suggest a therapeutic composition for treating cancer comprising the instantly claimed ingredients, whereby the apple cider vinegar, quinine, blackstrap molasses, and sulfur are each present therein in sufficient quantity so that the resulting composition has a therapeutic effect against cancer (nor a method of treating cancer therewith), as instantly claimed.

Again, to hasten prosecution, it is strongly suggested that claims 1-19 be canceled in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Christopher R. Tate', with a stylized, looping flourish above the name.

Christopher R. Tate
Primary Examiner
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